Passeo-35 PTA Catheter
Special 510(k) Premarket Notification
510(k) Summary

APR 2 3 2013

Name and Address of Sponsor:

BIOTRONIK, Inc.
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Lake Oswego, OR 97035

510(k) Contact Person and Phone Number:

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Date Prepared:

January 21, 2013

Device Name:

Proprietary Name:	Passeo-35
Common Name:	Percutaneous Transluminal Angioplasty (PTA) Catheter
Classification:	Class II (21 CFR 870.1250)
Classification Name:	Catheter, angioplasty, peripheral, transluminal
Product Code:	LIT

Predicate Device:

BIOTRONIK indicates Passeo-35 was previously cleared through 510(k) notification and it is its own predicate device for this Special 510(k) changes being effected labeling changes:

- BIOTRONIK's Passeo-35 PTA Catheter (K082933, cleared November 3, 2008).

General Description:

The Passeo-35 peripheral transluminal angioplasty (PTA) balloon catheter is indicated for dilatation of stenotic segments in peripheral vessels. One radiopaque marker is located at either end of the balloon to facilitate fluoroscopic visualization and positioning of the balloon catheter towards and across the lesion. The dilatation balloon is designed to inflate to a known diameter at a specific inflation pressure consistent with the compliance chart on the label. The balloon catheter includes a tapered soft tip to facilitate advancement of the catheter.

The balloon catheter shaft has two Luer ports at the proximal end. One port (inflation port) serves for connecting an inflation device to inflate/deflate the balloon. The other port (guidewire port) enables insertion of the guide wire. The balloon catheter is a dual lumen design with both lumens contained within one tube. The smaller lumen is the balloon inflation/deflation lumen. The larger lumen permits the use of guide wires with a maximum diameter of 0.035" to facilitate advancement of the Passeo-35 catheter towards and through the lesion(s) to be dilated. The balloon catheter is compatible with introducer sheath (introducer) sizes according to the recommendations on the label. The balloon catheter has a silicone coating to improve the trackability and pushability characteristics.

Indication for Use:

The indications for use statement may be found in **Appendix 01**.

This device is prescription only device as stated on the IFU, "Caution: Federal (USA) law restricts this device to sale by or on the order of a physician". The Passeo-35 peripheral dilatation catheter was cleared with the indication for use of, "The Passeo-35 peripheral dilatation catheter is indicated to dilate stenosis in the renal, iliac, femoral, popliteal and infrapopliteal arteries and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae."

Technological Characteristics

The subject device as the predicate device, Passeo-35 PTA Catheter (K082933, cleared November 3, 2008). The only differences pertain to the changes in the IFU and labeling, the materials, manufacture and technology have remained unchanged.

Nonclinical Test Data

The determination of substantial equivalency on this subject device does not rely upon the nonclinical test data. There is no nonclinical test data submitted in this application.

Clinical Test Data

The determination of substantial equivalency on this subject device does not rely upon the clinical data. There is no clinical data submitted in this application.

Conclusion

Based on the minor nature of the labeling changes, the subject Passeo-35 catheter is substantially equivalent to the predicate Passeo-35 catheter.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

April 23, 2013

BIOTRONIK, Inc.
c/o Mr. Jon Brumbaugh
Vice President, Regulatory Affairs & Compliance
6024 Jean Road
Lake Oswego, OR 97224

Re: K130161
Trade/Device Name: Passeo-35 PTA Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous catheter
Regulatory Class: Class II (two)
Product Code: LIT
Dated: January 21, 2013
Received: January 23, 2013

Dear Mr. Brumbaugh:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Matthew G. Hillebrenner

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K130161

Indications for Use

510(k) Number (if known): K130161

Device Name: Passeo-35 PTA Catheter

Indications For Use:

The Passeo-35 peripheral dilatation catheter is indicated to dilate stenosis in the renal, iliac, femoral, popliteal and infrapopliteal arteries and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Matthew G Hillebrenner